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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/765,725

01/26/2004

Michael J. Drews

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2546

23410 7590 12/21/2006  
Vista IP Law Group LLP  
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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/21/2006

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/765,725		DREWS ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Brian E. Pellegrino		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 and 36-53 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-22 and 36-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/8/05</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Group I invention and Specie G for the connector base and Specie IV for the crown assembly and Specie I for the guide channel in the reply filed on 10/2/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 3 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected specie, there being no allowable generic or linking claim.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,4,9 are rejected under 35 U.S.C. 102(e) as being anticipated by Yencho et al. (6776785). Fig. 11 shows a vascular assembly with a first base member **88** with a multi-lobular shape within a plane and a second annular body **88** above also

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having a multi-lobular shape complementary to the base. It can also be seen there is a plurality of connector elements spaced apart along the perimeter on both the base and upper body that are joined by a curve. It can be construed also that elements **90** are connecting members and a fully capable of connecting with a valve member. Please note the intended use carries no weight in the absence of any distinguishing structure.

Claims 1,2,4,5,7-16,18,21,22,36-41,43-47,49,52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Lane (6371983). Fig. 1 shows a heart valve assembly comprising an annular body **13** with a multi-lobular shape and containing multiple valve members or leaflets **15a,15b,15c**. Additionally there is a flexible cuff **17** attached to the base also comprising a multi-lobular shape. Fig. 3 illustrates that the outer frame or base member **25** has the cuff **17** attached thereto. It can be construed that since the base member is made of metal or plastic (col. 4, lines 8,9) it is rigid. As seen in Fig. 1 there is a plurality of connectors (3) spaced along the perimeter of the base member. Fig. 4 shows one of the connectors is a protrusion or pin **23** and the complementary connector is an aperture to receive the pin. Fig. 5 illustrates the second connecting member has apertures in the form of holes **26**. Since the slots or holes are oblong it can be construed that it permits sliding of the guide members **23** in the guide channels **26**. Lane discloses that the connectors are used to fasten the base member to the annular member or valve frame, col. 3, line 67, col. 4, lines 1-5,33,34,43,44. Lane also discloses that the multiple strips are used as guides or alignment markers to affix the base and annular body together, col. 4, lines 39-42,49-52. Lane additionally

discloses that in some heart valve assemblies a tether can be used to align the annular body with the base member, col. 7, lines 60-67.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lane '983 in view of Griffin et al. (6241765). Lane is explained supra. However, Lane fails to disclose the pin is resilient. Griffin et al. teach (Fig. 7) a resilient pin **91** for use with a heart valve prosthesis, col. 5, lines 24,25. It would have been obvious to one of ordinary skill in the art to utilize a flexible pin as taught by Griffin et al. with the prosthesis of Lane such that it easily is inserted in the valve assembly without much force that would move the prosthesis during insertion.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lane '983 in view of Peredo (6409759). Lane is explained above. However, Lane fails to disclose the use of a marker with the prosthetic valve. Peredo teaches that markers can be placed on a base member to properly align the implant in the body, col. 6, lines 54-65. It would have been obvious to one of ordinary skill in the art to utilize markers as taught by Peredo with the prosthesis of Lane such that it ensures proper placement and alignment of the valve prosthesis in the patient.

Claims 19,20,42,48,50,51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane '983 in view of Macoviak (6893459). Lane is explained as before. However, Lane fails to disclose the use of a ratchet mechanism for aligning the annular body with the base member. Macoviak teaches (Figs. 3,4) that one of the base member or annular body has a guide member **67** and the other component has ratchets **43** and the guide member in a guide channel **77**. Macoviak also teaches that the ratcheting provides the surgeon the ability with controlled placement of the valve member at the annulus, col. 6, lines 20-31. It would have been obvious to one of ordinary skill in the art to utilize a ratcheting system as taught by Macoviak with the prosthesis of Lane such that it enables the heart valve implant to be manipulated into the proper position at the implantation site. Regarding claim 48, it can be construed that the portion of the guide member that extends into the guide channel has a rectangular cross-section.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (7:30am-5pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive style with a large, stylized "B" and "P".

TC 3700, AU 3738